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EXAMINER

WEISS JR, JOSEPH FRANCIS

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 09/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/646,140

Applicant(s)
Von Schuckmann et al.

Examiner
Joseph Weiss

Art Unit
3761



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 5, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 17, and 18 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 17, and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Art Unit: 3761

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-14 & 17-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 ends with the language “regardless of which way the user inserts the blister pack” inserts the blister pack into what?

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-11, 14, 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friberg in view of Von Schuckmann (WO 97/40876).

In regards to claim 1, Friberg discloses a blister pack device comprising a body (10) which includes a first (11) and second surface (12) having a plurality of blisters containing medicament (16), wherein the blisters on the surfaces are arranged in rows running parallel to a longitudinal

Art Unit: 3761

axis of the blister pack device (see any fig) and the blisters in each row in the first surface are configured to sit between the blisters in a co-operating row in the second surface (see figs 1e & 2d), the blisters in the first and second surface being rotationally symmetrically disposed about a longitudinal axis of the blister pack device (see any fig), and a support unit (21, 22 & 31) for enclosing the blister pack device, but does not disclose the support element having a plurality of openings in one surface which corresponds with the blisters in the first OR second surface adjacent thereto regardless of which way the user inserts the blister pack, But Von Schuckmann discloses such. (See figs 1-4, 17-27 and supporting text). The references are analogous since they are from the same field of endeavor, the medicament dispensing arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Von Schuckmann and used them with the device of Friberg. The suggestion/motivation for doing so would have been because Von Schuckmann discloses the use of such a device with a blister pack and Friberg discloses a blister pack. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

Art Unit: 3761

In regards to claim 2, Friberg discloses the blisters in one row of the surface being off-set/staggered with respect to the blisters in an adjacent row of that surface. (See figs 1a, 1d-1e, 2a, 2c-2d).

In regards to claim 3, Friberg discloses the blisters in the first and second surfaces configured such that the blisters of the first surface (11) are disposed in one or both spaces between and adjacent to the blisters on the second surface (12) .(see figs 1e & 2d)

In regards to claim 4, Friberg discloses the plurality of surfaces as being defined by separate elements. (11 & 12, embodiment in fig 1)

In regards to claim 5, Friberg discloses the plurality of surfaces as being defined by a single element.(10, embodiment in fig 2)

In regards to claim 6, Friberg discloses a blister pack device and a support member which supports a the first and second surfaces. (20/30)

In regards to claim 7, Friberg discloses the support member comprising a frame. (30)

In regards to claim 8, the suggested device substantially discloses the instant application's claimed invention to include the blister pack unit of claim 6, but does not explicitly disclose a suction tube, including a cutting assembly configured for insertion into a blister and an inhalation channel through which powder can be inhaled. However, Von Schuckmann disclose such ("S," note the terminal end of S that has cutting abilities). The references are analogous since they are from the same field of endeavor, the medicament dispensing arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to

Art Unit: 3761

have taken the features of Von Schuckmann and used them with the device of Friberg. The suggestion/motivation for doing so would have been because Von Schuckmann discloses the use of such a device with a blister pack and Friberg discloses a blister pack. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 9, the suggested device does not disclose the use of a "clip" as part of the body to retain the suction tube. However, Von Schuckmann disclose a body with a suction tube retention means (33/34) which is an interchangeable functional mechanical equivalent of the clip. The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Von Schuckmann and used them with the device of Friberg. The suggestion/motivation for doing so would have been to keep the suction tube from being lost. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Also, it is noted that applicant's specification does not set forth the clip, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Art Unit: 3761

Accordingly, the examiner considers the selection of a clip to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 10, the suggested device discloses the use of an interconnecting member (6) for connecting the suction tube to the blister pack unit to prevent suction tube separation from the blister pack unit.

In regards to claim 11, the reference noted above substantially disclose the claimed invention except for the use of a line.

It is noted that applicant's specification does not set forth the line, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to claim 14, Friberg substantially discloses the instant application's claimed invention to include the blister pack unit of claim 6, but does not explicitly disclose the blister pack being combined with an inhaler. However, Von Schuckmann disclose such (See any fig).

Art Unit: 3761

The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Von Schuckmann and used them with the device of Friberg. The suggestion/motivation for doing so would have been because Von Schuckmann discloses the use of such a device with a blister pack and Friberg discloses a blister pack. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 17, the suggested device discloses the support unit comprising a housing (1) in which the blister pack can be received with at least one wall (6) of the housing including the openings.

In regards to claim 18, the suggested device discloses the support unit further comprising a cover member (33) which can enclose the suction member when closed but not the openings.

It is noted that applicant's specification does not set forth this feature, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Art Unit: 3761

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patentably distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patentably distinct inventive step, barring a convincing showing of evidence to the contrary.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Art Unit: 3761

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 8-14 & 17-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-53 of U.S. Patent No. 6401712 in view of Friberg (PCT WO 98/00351).

US patent '712 substantially discloses the instant application's claimed invention to include an inhaler, which can also be characterized as a suction tube (S) with a cutting assembly (cutting terminus of S) configured for insertion into a blister and the suction tube has an inhalation channel (note interior of S), but does not explicitly disclose the blister pack of claims 6 or 8. However, Friberg & Von Schuckman disclose such, see the rejections to claims 1 & 6 above which are herein incorporated by reference. The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Friberg and used them with the device of Von Schuckmann. The suggestion/motivation for doing so would have been because Von Schuckmann discloses the use of such a device with a blister pack and Friberg discloses a blister pack. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather

Art Unit: 3761

than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

7. Claims 8-14 & 17-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6520179 in view of Friberg (PCT WO 98/00351).

US patent '179 substantially discloses the instant application's claimed invention to include an inhaler, which can also be characterized as a suction tube (7) with a cutting assembly (cutting terminus of 7) configured for insertion into a blister and the suction tube has an inhalation channel (note interior of 7), but does not explicitly disclose the blister pack of claims 6 or 8. However, Friberg and von Schuckman disclose such, see the rejections to claims 1 & 6 above which are herein incorporated by reference. The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Friberg and used them with the device of Von Schuckmann. The suggestion/motivation for doing so would have been because Von Schuckmann discloses the use of such a device with a blister pack and Friberg discloses a blister pack. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention. Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

Art Unit: 3761

Response to Arguments

8. Applicant's arguments with respect to claims 1-14 & 17-20 have been considered but are moot in view of the new ground(s) of rejection.

In regards to the 35 USC 112 rejection, applicant's amendment is proper and responsive and resolves the issue, therefore the rejection is withdrawn.

In regards to the 35 USC 102 rejection, applicant's amendment is proper and responsive and resolves the issue, therefore the rejection is withdrawn.

In regards to the 35 USC 103 rejection, applicant's amendment is proper and responsive, but does not resolve the issue of obviousness.

In regards to the double patenting rejections, applicant's amendment is not proper and not responsive, no terminal disclaimer nor remarks addressing the double patenting rejections are present in the amendment, and considers such to be an acquiescence as to the merits of the rejection.

The examiner acknowledges that applicant has set forth his personal biased belief as to what the references disclose, however the examiner's lack of comment on this personal biased belief is not to be construed as an acquiescence or agreement with such, instead the examiner relies solely upon the prior art references as published and interpreted using the legal standard of one of ordinary skill in the relevant art as the determination as to their content and teachings.

Regarding applicant's conclusory argument that the prior art provides "no inkling whatsoever [sic] of staggering blisters in first and second surfaces, to provide for compactness, at

Art Unit: 3761

the same time as relying on rotational symmetry to that the blisters [sic] the first surface will align with the openings in the support unit when the first surface is in position, and the blisters in the second surfaces will align with the openings in the support unit when the second surface is in position," no legal analysis in the form of a reasoned basis is presented by applicant to reach the conclusion of "no inkling whatsoever [sic]." The case law and the statutes do not present this language as being any sort of legal standard for determining the legal viability of obviousness, therefore such a statement serves only as an indicator of the bias personal and conclusory beliefs on the part of applicant.

Furthermore, the language subsequent to the phrase "no inkling whatsoever[sic]" is not the verbatim language of claim one as currently amended, further brining into question the legal relevancy of the statement. Specifically, the argument seems to assert that the blister pack of the prior art does not possess rotational symmetry, yet the device is symmetrical in design and can be rotated by a user about an axis of its symmetrical design. Also, applicant's language suggests that some sort of design feature/function of simultaneity of first and second surface to openings to blister alignment exists in the currently claimed invention, such is not the case. The use of the disjunctive "or" in the next to the last line in the phrase "first or second surface" is a claiming of function of alignment with one or the other and not both simultaneously as applicant's argument asserts. Please note:

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies are not recited in the

Art Unit: 3761

rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Joseph F. Weiss, Jr., whose telephone number is (703) 305-0323. The Examiner can normally be reached from Monday-Friday from 8:30 AM to 4:30 PM.

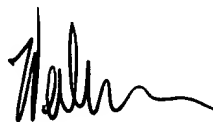
Art Unit: 3761

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Weilun Lo, can be reached at telephone number (703) 308-1957. The official fax number for this group is (703) 305-3590 or x3591.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858.

A handwritten signature in black ink, appearing to read "J. Weiss", with a long horizontal flourish extending to the right.

September 25, 2003

A handwritten signature in black ink, appearing to read "Weilun Lo", with a long horizontal flourish extending to the right.

**WEILUN LO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700**